K090012

Chapter III 510(k) Summary

The assigned 510(k) Number is: _____

JUN 11 2009

1. Date Prepared: December 31, 2008

2. Sponsor Information

ShanDong WeiGao Group Medical Polymer Co., Ltd
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3. Submission Correspondent

Ms. Diana Hong
Mr. Lee Fu
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, Zhongshan Zhongxin Mansion
No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, 200030, China

4. Device Name and Classification:

Device Trade Name: Disposable infusion set
Device Common Name: Disposable infusion device
Device Classification Name: Set, administration, intravascular
Product Code: FPA
Regulation Number: 880.5440
Device Class: II

5. Predicate Device Identification:

Tianjin Medis Disposable Infusion Set
K-number: K060082

6. Intended Use:

Disposable infusion set is used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

7. Device Description:

The applicant device is plastic, single-use, sterile disposable infusion device, which is intended to be used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

The protective cap o is intended to protect the needle; The puncturing needle is made of Polyethylene and used to pierce the container; the catheter is made of Polyvinyl chloride and used to connect various components, there is no DEHP used in the proposed device; the drip is transparent so that the user can observe the dropping condition of the medical solution, and it has a filtration mesh which can prevent the micro particle with diameter larger than 200 um to from entering human vessel; Flow regulator is used to adjust the flow rate from zero to maximum; Infusion needle is inserted into human vessel for medical solution transfusion, it is made of stainless steel.

The proposed device is provided sterilized.

8. Test Conclusion resignation

Laboratory testing was conducted to validate and verify that disposable infusion set met all design specifications and was substantially equivalent to the predicate device.

9. Substantially Equivalent Conclusion:
The subject device, disposable infusion set is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2009

Shan Dong Wei Gao Group Medical Polymer Products
C/O Ms. Diana Hong
General Manager
Shanghai Midlink Business Consulting Company, Limited
Suite 8D, No. 19, Line 999,
Zhongshan No.2 Road (S)
Shanghai, 200030,
CHINA

Re: K090012
Trade/Device Name: Disposable Infusion set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 21, 2009
Received: May 26, 2009

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090012

Indication for Use

510(k) Number:

Device Name: Disposable Infusion Set

Indications for Use:

Disposable Infusion Set is used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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